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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 92F-0443]

Indirect Food Additives: Adhesives and Components of Coatings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen polysiloxane and dimethylmethylhydrogen polysiloxane using a platinum catalyst. FDA is also amending the food additive regulations to provide for the safe use of 3,5-dimethyl-1-hexyne-3-ol, 1-ethynylcyclohexene, bis(methoxymethyl)ethyl maleate, methylvinyl cyclosiloxane, and tetramethyltetravinylcyclotetrasiloxane as optional polymerization inhibitors. This action is in partial response to a petition filed by Dow Corning Corp.

DATES: The regulation is effective (*insert date of publication in the Federal Register*); written objections and requests for a hearing by (*insert date 30 days after date of publication in the Federal Register*).

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3091.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 12, 1993 (58 FR 8290), FDA announced that a petition (FAP 3B4346) had been filed by Dow Corning Corp., P.O. Box 994, Midland, MI 48686-0994. The petition proposed to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300), § 175.320 *Resinous and polymeric coatings for polyolefin films* (21 CFR 175.320), and § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen-containing polysiloxane and dimethylmethylhydrogen polysiloxane polymers using a platinum catalyst. The petition further proposed that the food additive regulations be amended to provide for the safe use 3,5-dimethyl-1-hexyne-3-ol, 1-ethynylcyclohexene, bis(methoxymethyl)ethyl maleate and methylvinyl cyclosiloxane as optional polymerization inhibitors. Additionally, the petition proposed that the regulations be amended to provide for the safe use of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one mixture, optionally containing magnesium nitrate, as an antimicrobial agent for emulsion-based silicone coating formulations.

Subsequent to the filing of the petition, the petitioner requested that tetramethyltetravinylcyclotetrasiloxane be included in the petition. Therefore, in a notice published in the **Federal Register** of July 2, 1998 (63 FR 36246), FDA announced that it was amending the filing notice of February 12, 1993, to indicate that the petitioner was also proposing that the food additive regulations be amended to provide for the safe use of tetramethyltetravinylcyclotetrasiloxane as an optional polymerization inhibitor in the manufacture of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen-containing polysiloxane and dimethylmethylhydrogen polysiloxane polymers using a platinum catalyst.

In 1996, Congress enacted the Food Quality Protection Act (the FQPA). As a result of certain changes made by that law, antimicrobial formulations used in or on food contact articles were

made subject to regulation as pesticide chemicals by the U.S. Environmental Protection Agency. Thus, after the FQPA, the proposed use of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one mixture, with magnesium nitrate as an optional ingredient, intended for use as an antimicrobial agent for emulsion-based silicone coating formulations was no longer under the jurisdiction of FDA. Because FDA lacked the authority to regulate this substance for the antimicrobial use, the agency did not complete its review of the safety of this additive.

Congress recently passed the Antimicrobial Regulation Technical Corrections Act of 1998 (the ARTCA) (Pub. L. 105–324) that reverses some of the jurisdictional changes made by the FQPA. As a result of the ARTCA, the antimicrobial use of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one mixture, with magnesium nitrate as an optional ingredient, is once again subject to regulation by FDA as a food additive. The safety of the proposed use of this substance will be considered by FDA and the agency's decision announced in a subsequent issue of the **Federal Register**.

As noted, the petition proposed to amend § 176.170, however, because the petitioned additives will be listed under § 175.300(b)(3) they may, by cross-reference, be used under § 176.170(b)(2). Therefore, this action does not include an amendment that would establish a separate listing for the additives under § 176.170(b)(2).

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of each additive is safe, that each additive will have its intended technical effect, and therefore, that the regulations in §§ 175.300 and 175.320 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents

any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this action as announced in the amended notice of filing for FAP 3B4346 published in the **Federal Register** of July 2, 1998 (63 FR 36246). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before *(insert date 30 days after date of publication in the **Federal Register**)*, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 175.300 is amended in paragraph (b)(3)(xxviii)(a) by alphabetically adding an entry to read as follows:

§ 175.300 Resinous and polymeric coatings.

* * * *

(b) * * *

(3) * * *

(xxviii) * * *

(a) * * *

Siloxane resins originating from the platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. No. 68083–18–1 and CAS Reg. No. 68083–19–2) with methylhydrogen polysiloxane (CAS Reg. No. 63148–57–2) and dimethylmethylhydrogen polysiloxane (CAS Reg. No. 68037–59–2), where the platinum content does not exceed 150 parts per million. The following substances may be used as optional polymerization inhibitors:

3,5-Dimethyl-1-hexyne-3-ol (CAS Reg. No. 107–54–0), at a level not to exceed 0.53 weight-percent;

1-Ethynylcyclohexene (CAS Reg. No. 931–49–7), at a level not to exceed 0.64 weight-percent;

Bis(methoxymethyl)ethyl maleate (CAS Reg. No. 102054–10–4), at a level not to exceed 1.0 weight-percent;

Methylvinyl cyclosiloxane (CAS Reg. No. 68082–23–5); and

Tetramethyltetravinylcyclotetrasiloxane (CAS Reg. No. 2554-06-5).

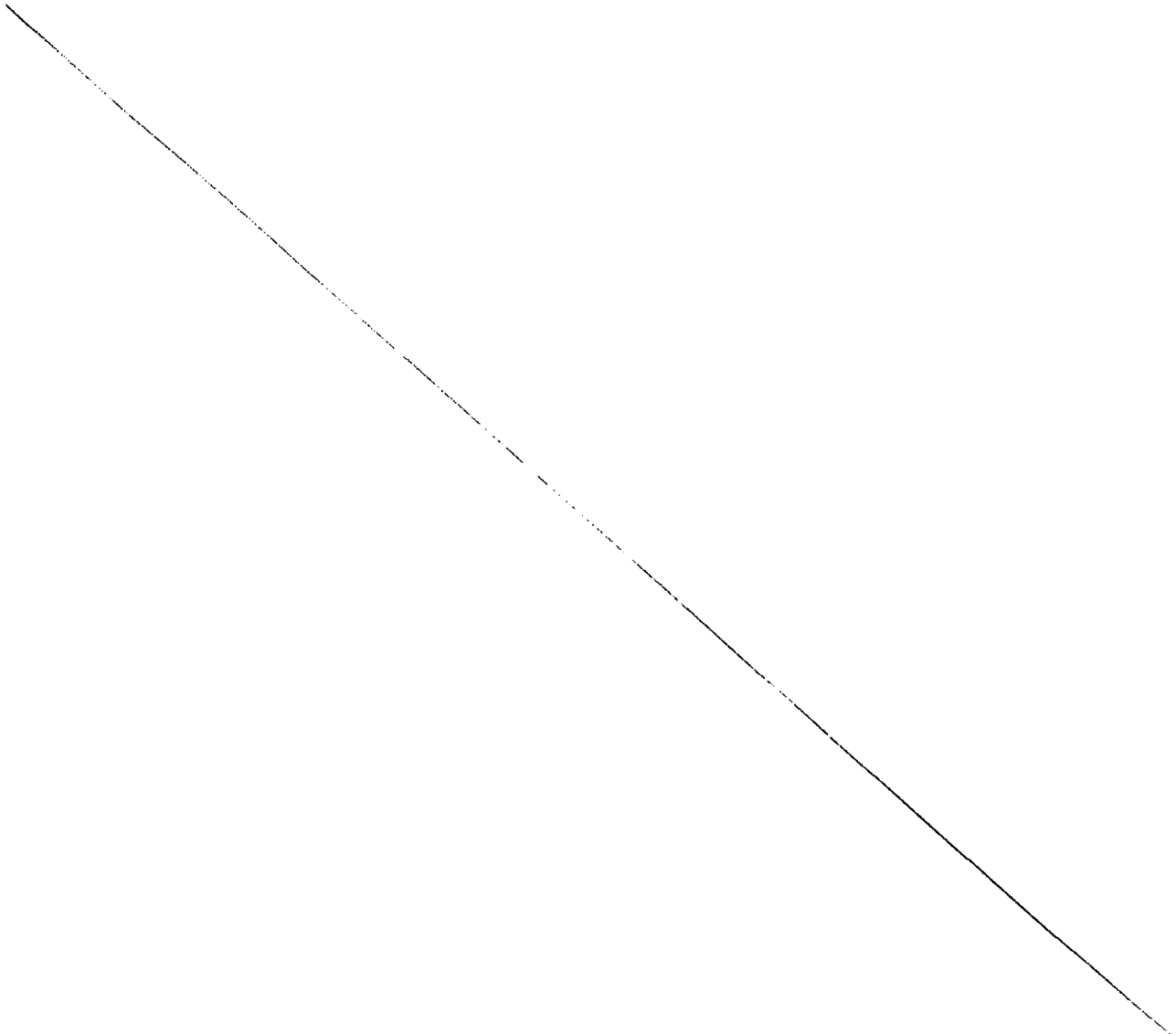
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3. Section 175.320 is amended in the table in paragraph (b)(3) in item (i) by alphabetically adding an entry under the headings “List of substances” and “Limitations” to read as follows:

§ 175.320 Resinous and polymeric coatings for polyolefin films.

(b) * * *

(3) * * *



List of substances	Limitations
(i) * * * Siloxanes and silicones: platinum-catalyzed reaction product of vinyl-containing dimethylpolysiloxane (CAS Reg. No. 68083-18-1 and CAS Reg. No. 68083-19-2) with methylhydrogen polysiloxane (CAS Reg. No. 63148-57-2) and dimethylmethylhydrogen polysiloxane (CAS Reg. No. 68037-59-2). The following substances may be used as optional polymerization inhibitors: 3,5-Dimethyl-1-hexyne-3-ol (CAS Reg. No. 107-54-0), at a level not to exceed 0.53 weight percent; 1-Ethynylcyclohexene (CAS Reg. No. 931-49-7), at a level not to exceed 0.64 weight percent; Bis(methoxymethyl)ethyl maleate (CAS Reg. No. 102054-10-4), at a level not to exceed 1.0 weight percent; Methylvinyl cyclosiloxane (CAS Reg. No. 68082-23-5); and Tetramethyltetravinylcyclotetrasiloxane (CAS Reg. No. 2554-06-5).	Platinum content not to exceed 150 parts per million.

* * * * *

Dated: 12/14/98

December 14, 1998

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

L. Robert Lake

L. Robert Lake
 Director
 Office of Policy, Planning and Strategic Initiatives
 Center for Food Safety and Applied Nutrition

Jen Windsor

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